Dated: March 20, 2012.

Ron A. Otten,

Director, Office of Scientific Integrity, Office of the Associate Director for Science (OADS), Office of the Director, Centers for Disease Control and Prevention.

[FR Doc. 2012–7351 Filed 3–26–12; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2012–N–0273]

Agency Information Collection Activities; Proposed Collection; Comment Request; Experimental Study of Graphic Cigarette Warning Labels

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal Agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on the Experimental Study of Graphic Cigarette Warning Labels that is being conducted in support of the graphic label provision of the Family Smoking Prevention and Tobacco Control Act (the Tobacco Control Act).

DATES: Submit either electronic or written comments on the collection of information by May 29, 2012.

ADDRESSES: Submit electronic comments on the collection of information to *http://www.regulations.gov.* Submit written comments on the collection of information to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Daniel Gittleson, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50–400B, Rockville, MD 20850, 301–796–5156, *Daniel.Gittleson@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501–3520), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Experimental Study of Graphic Cigarette Warning Labels—(OMB Control Number 0910–0668)—Extension

Tobacco products are responsible for more than 400,000 deaths each year. The Centers for Disease Control and Prevention report that approximately 46 million adults smoke cigarettes in the United States, even though this behavior will result in death or disability for half of all regular users. Paralleling this enormous health burden is the economic burden of tobacco use, which is estimated to total $193 billion annually in medical expenditures and lost productivity. Curbing the significant adverse consequences of tobacco use is one of the most important public health goals of our time. One way to do this is through health warnings that describe and graphically depict the harm caused by cigarette use causing individuals to think harder about the choice to use tobacco.

On June 22, 2009, the President signed the Tobacco Control Act (Public Law 111–31) into law. The Tobacco Control Act granted FDA authority to regulate the manufacture, marketing, and distribution of tobacco products to protect the public health generally and to reduce tobacco use by minors. Section 201 of the Tobacco Control Act, which amends section 4 of the Federal Cigarette Labeling and Advertising Act (15 U.S.C. 1333), requires FDA to issue ''regulations that require color graphics depicting the negative health consequences of smoking to accompany the label statements specified in subsection (a)(1).'' FDA conducts research relating to tobacco products under its statutory authority in section 1003(d)(2)(C) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 393(d)(2)(C)), as amended by the Tobacco Control Act, to conduct research ''relating to foods, drugs, cosmetics, devices, and tobacco products in carrying out the act.'' The study proposed here is an effort by FDA to collect data concerning graphic warnings on cigarette packages and their impact on consumer perceptions, attitudes, and behavior with respect to smoking.

On June 22, 2011, FDA issued a final rule in the **Federal Register** of June 22, 2011 (76 FR 36628) entitled ''Required Warnings for Cigarette Packages and Advertisements,'' which specified nine graphic images to accompany the new textual warnings for cigarettes. Although the rule was scheduled to become effective 15 months after it issued, a federal district court has permanently enjoined FDA from implementing the rule in its current form. FDA has appealed this decision to the U.S. Court of Appeals of the District of Columbia. FDA expects that the information that FDA proposes to collect will be relevant to FDA's regulation of cigarette warnings no matter the outcome of the current litigation.

The study, the Experimental Study of Graphic Cigarette Warning Labels, is a voluntary annual experimental survey of consumers. The purpose of the study is to assess the effectiveness of various graphic warnings on cigarette packs for achieving three communication goals: (1) Conveying information about various health risks of smoking, (2) encouraging cessation of smoking among current smokers, and (3) discouraging initiation of smoking among youth and former smokers. The study will collect data from various groups of consumers, including current smokers aged 13 years and older, former smokers aged 13 years and older, and non-smokers aged between 13 and 25 years who may be susceptible to initiation of smoking. The

study goals are to: (1) Measure consumer attitudes, beliefs, and intended behaviors related to cigarette smoking in response to graphic warning labels; (2) determine whether consumer responses to graphic warning labels differ across various groups based on smoking status, age, or other demographic variables; and (3) evaluate the relative effectiveness of various graphic images associated with each of the nine warning statements specified in the Tobacco Control Act for achieving each of the communication goals. The information collected from the study is necessary to inform the Agency's efforts to implement the mandatory graphic warnings required by the Tobacco Control Act.

The experimental study data will be collected from participants of an Internet panel of approximately 43,000 people. Participation in the experimental study is voluntary.

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Portion of study	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Pretest	60	1	60	0.5	30
Screener	15,000	1	15,000	0.016	240
Experimental Survey	5,400	1	5,400	0.5	2,700
Total					2,970

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

FDA's burden estimate is based on prior experience with Internet panel experiments similar to the study proposed here. Sixty panel members will take part in a pretest of the study, estimated to last 30 minutes (0.5 hours), for a total of 30 hours. Approximately 15,000 respondents will complete a screener to determine eligibility for participation in the study, estimated to take 1 minute (0.016 hours), for a total of 240 hours. Fifty-four hundred respondents will complete the full study, estimated to last 30 minutes, for a total of 2,700 hours. The total estimated burden is 2,970 hours (30 hours plus 240 hours plus 2,700 hours).

Dated: March 21, 2012.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2012–7289 Filed 3–26–12; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2012–N–0001]

Development of Animal Models of Pregnancy To Address Medical Countermeasures for Influenza in the ''At Risk'' Population of Pregnant Women: Influenza as a Case Study; Public Workshop

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop.

The Food and Drug Administration's (FDA) Center for Drug Evaluation and Research and FDA's National Center for Toxicological Research are announcing a 2-day public workshop entitled ''Development of Animal Models of Pregnancy To Address Medical Countermeasures for Influenza in the 'At Risk' Population of Pregnant Women: Influenza as a Case Study.'' The purpose of this workshop is to provide a forum to carefully consider scientific issues related to selecting animal models for use in evaluating medical influenza countermeasures (anti-influenza drugs) that may be given during pregnancy. Specifically, this workshop will address experimental design issues in selecting the most appropriate animal model that mimics human pregnancy. The goal is to use this model to evaluate how pregnancy changes the pharmacokinetics of anti-influenza drugs in animals and compare those changes to the changes that are known to occur in human pregnancy. The data obtained from using this model may enhance the knowledge base needed to extrapolate the effects of pregnancy on other medical countermeasures.

DATES: *Date and Time:* The public workshop will be held on April 30, 2012, from 8:30 a.m. to 5 p.m., and on May 1, 2012, from 8:30 a.m. to 5 p.m.

Location: The public workshop will be held at the FDA White Oak Campus, 10903 New Hampshire Ave., Central Shared Use (CSU) Bldg. 2, rm. 2047, Silver Spring, MD 20993–0002. Entrance for the public meeting participants (non-FDA employees) is through Building 1, where routine security check procedures will be performed, a visitor badge will be issued, and an escort will be provided to the meeting room. Government-issued identification will be needed. For additional information on parking and security, please refer to *http://www.fda.gov/AboutFDA/WorkingatFDA/BuildingsandFacilities/WhiteOakCampusInformation/ucm241740.htm.*

Contact Person: For questions about the workshop, please contact Cindy de Sales, *cindy@tepgevents.com,* 240–316–3207.

Registration: There is no fee to attend the public workshop, but attendees must register in advance. Space is limited, and registration will be on a first-come, first-served basis. Persons interested in attending this workshop must register online at *http://fda.contractmeetings.com* before April 16, 2012. Non-U.S. citizens are subject to additional security screening, and they should register as soon as possible. For those without Internet access, please contact Cindy de Sales (see *Contact Person*) to register. Onsite registration is not available.

If you need special accommodations due to a disability, please contact Cindy de Sales (see *Contact Person*) at least 7 days in advance.

SUPPLEMENTARY INFORMATION: During seasonal and pandemic influenza outbreaks, pregnant women generally have greater morbidity and mortality than other adults. The data from the 2009 H1N1 influenza pandemic suggested that pregnant women were at increased risk for medical complications. There is limited information regarding the efficacy, pharmacokinetics, optimal dosing, and side effects of anti-influenza drugs that may need to be used during pregnancy. The same is true for most drugs to treat diseases due to other infectious agents.

The anti-influenza drugs have been selected for further study because the influenza virus can infect pregnant women, and oseltamivir, an anti-